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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,476	02/23/2004	Alan R. Fritzberg	295.044US3	1730

21186 7590 04/13/2005

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EXAMINER	
JONES, DAMERON	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/784,476	FRITZBERG ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/23 & 6/7 & 6/21 & 8/2/04 and 2/14/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52,53,80 and 81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52,53,80 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/21/04 & 8/2/04 &* 2/14/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 2/23/04 wherein the specification was amended. In addition, the Examiner acknowledges the amendment filed 6/7/04 wherein claims 1-51, 54-79, and 82-85 were canceled and claim 81 was amended.

Note: Claims 52, 52, 80, and 81 are pending.

APPLICANT'S INVENTION

2. The instant invention is directed to a method of treating non-cancerous diseases in or near bone and a method of treating a subject afflicted with a hematopoietic genetic defect as set forth in independent claims 52 and 80.

STATUTORY DOUBLE PATENTING

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 52, 53, 80, and 81 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 52, 53, 80, and 81 of copending Application No. 10/882,054. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

OBVIOUSNESS-TYPE DOUBLE PATENTING

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 52, 53, 80, and 81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20, 29, and 34 of copending Application No. 10/882,054. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of treating non-cancerous disorders with a radionuclide-ligand complex. The claims differ in that the instant invention discloses a specific range of radiation units (claim 52), specific non-cancerous diseases (claim 53), and list a method of treating hematopoietic genetic defects in a separate claim (independent claim 80). However, a skilled practitioner in the art would recognize that claims 20, 29, and 34 of 10/882,054 is more general than the claims of the instant invention and actually encompasses the subject matter of claims 52, 53, 80, and 81 of the instant invention. In particular, while claim 20 of 10/882,054 is directed to a non-cancerous disorder as claim 52 of the instant invention; claim 34 of 10/882,054 is directed to a subject afflicted with cancer (i.e., leukemia) which is a hematopoietic genetic defect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 80 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/041,828. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a hematopoietic genetic defect. In particular, a skilled practitioner in the art would recognize that leukemia is a hematopoietic genetic defect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 80 and 81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 60 and 61 of copending Application No. 10/615,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a hematopoietic genetic defect wherein a radionuclide-ligand complex is administered and claim 61 of 10/615,484 is directed to specific diseases/conditions. However, a skilled practitioner in the art would recognize that sickle cell anemia, for example, is a hematopoietic genetic defect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 SECOND PARAGRAPH REJECTIONS

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 80 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 80, lines 2-3, is ambiguous because of the phrase 'in need of such treatment bone marrow suppressing dosage'. In particular, in line 1, the claim is directed to all hematopoietic genetic defects, not just those of the bone. Hence, it is unclear if Applicant intended to write 'hematopoietic genetic defect in or near bone' (line 1) for consistency in the claim. Also, should the phrase in need of such treatment bone marrow suppressing dosage' be in need of a bone marrow suppressing dosage'? Please clarify in order that one may readily ascertain what is being claimed.

Note: Since claim 81 depends from claim 80 which is ambiguous, claim 81 is also vague and indefinite.

103 REJECTIONS

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 52, 80, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al (US Patent No. 4,853,209).

Kaplan et al disclose a method of suppressing bone marrow which comprises administering at least one radionuclide composition. The composition is selected form at leas one radionuclide such as Sm-153, Gd-519, and Ho-166 and at least one ligand such as EDTMP, DTPMP, HEEDTMP, NTMP, and TTHMP having a phosphonic acid moiety (see entire document, especially, abstract; column 2, lines 18-42; column 1, lines 55-63; column 3, lines 29-34; column 4, lines 15-21; columns 12-14, claims 1-20). In addition, it is disclose that in the art it is known to use agents that suppress or eradicate bone marrow to treat subjects with cancers such as leukemia, lymphomas, myelomas, and Hodgkin's disease as well as subject having genetic disorders such as sickle cell anemia and thalassemia (column 1, lines 11-17; column 1, lines 26-49). Kaplan et al disclose that for disease states wherein the treatment requires bone marrow suppression, it is advantageous to use their inventio9n since it provides a means of achieving selective reduction in the hematopoietic stem cell population *without* having to resort to total body irradiation; thus, less damage to non-target tissues (column 2, lines 58-68). Also, Kaplan et al disclose Example 6 (column 8) wherein Sm-153 having a specific activity of about 0.5 to about 3.0 Curies/gram is utilized. Thus, both Kaplan et al and Applicant contain overlapping subject matter.

In particular, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat a non-cancerous disease in or near bone and a subject afflicted with a hematopoietic genetic defect because Kaplan et al disclose that its invention is concerned with suppressing bone marrow wherein a radionuclide and at least one chelating agent are administered to a subject. In the summary of the

invention, it is disclosed that the phrase 'bone marrow suppression' encompasses temporary or permanent reduction of the hematopoietic stem cell population (column 2, lines 53-57). In addition, in the background of the invention, it is disclosed that agent s that suppress or eradiate bone marrow may be used to treat subjects having Hodgkin's disease as well as subjects having sickle cell anemia and thalassemia. Hence, a skilled practitioner in the art using any standard medical dictionary (i.e., The Harper Collins Illustrated Medical Dictionary, 1993, page 204) would recognize that Hodgkin's disease, for example, is a non-cancerous disease since it is defined as a disease of lymphatic tissue characterized by painless enlargement of the lymph nodes with or without systemic symptoms such as fever, sweats, weight loss, and lassitude. Thus, Hodgkin's disease would be considered as a non-cancerous disease. Also, the skilled artisan using a standard medical dictionary (i.e., The Harper Collins Illustrated Medical Dictionary, 1993, pages 16-17 and 475) would recognize that conditions such as thalassemia and sickle cell anemia are non-cancerous conditions that are present in or near bone (i.e., a defect of the red blood cells). Furthermore, a skilled practitioner in the art would recognize that the specific activity of Sm-153 disclose in Example 6 (column 8) encompass the megabecquerels per kilogram ranges set forth in independent claims 52 and 80.

SPECIFICATION

13. The disclosure is objected to because of the following informalities: (1) Page 20 of the instant application contains personal notes in the margin. (2) In addition,

Applicant is respectfully requested to clarify the record. In particular, provisional application 60/143,780 is listed as being filed on 6/13/99 in the declaration. However, US PTO records indicate that the application was filed 7/13/99.

Appropriate correction is required.

COMMENTS/NOTES

14. Applicant is respectfully requested to supply the year to the following documents which are not present on the information disclosure statements filed 6/21/04 in the next correspondence to the Examiner. (1) S. C. Srivastava et al (sheet 12 of 14 filed 6/21/04). (2) J. Weininger (sheet 13 of 14 filed 6/21/04). (3) S. R. Thomas (sheet 13 or 14 filed 6/21/04).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

April 7, 2005